

Serial No. 09/125,747

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TORO 0101 PUS

**In the Title:**

Please change the title to read as follows:

IMMUNODULATORY COMPLEX AND USE THEREOF  
IN HELICOBACTER DISEASES

RECEIVED  
FEB 12 2004  
TECH CENTER 1600/2900

**In the Specification:****Please replace Paragraph 2, lines 8-10, on Page 1 with the following:**

{MARSHALL B. J., WARREN Jr., Unidentified curved bacilli in the stomach of the patients with gastritis and peptic ulceration *Lancet* 1984: i:1311-4)}.

**Please replace Paragraph 3, lines 11-13, on Page 1 with the following:**

{MÉGRAUD F., *Helicobacter pylori*, the most important bacterium among the mucus bacteria, *La letter de l'infectiologue* 1993; 8 (suppl. 4): 151-9)}.

**Please replace Paragraph 4, lines 19-20, on Page 3 with the following:**

{PARSONNET J: *Helicobacter pylori* and gastric cancer. *Gastroenterol Clin North Am* 1993, 22:89-104.

**Please replace Paragraph 6, lines 26-27, on Page 3 with the following:**

MOHANDAS, *Helicobacter pylori* and lymphoma, *N Eng J Med* 1994: 331:746-7}.

**Please replace Paragraph 1, lines 1-4, on Page 4 with the following:**

{PETERSON P.K., VERHOEF J., SCHMELING D. & QUIE P.G.: Kinetics of phagocytosis and bacterial killing by human polymorphonuclear leucocytes and monocytes, *J. Infec. Dis.* 136:502-509, 1977.

**Please replace Paragraph 2, lines 5-8, on Page 4 with the following:**

KIEHLBAUCH J.A., ALBACH R.A., BAUM I.K., CHANG K.P. Phagocytosis of *Campylobacter jejuni* and its intracellular survival in mononuclear phagocytes, *Infect Immun* 1985; 48:446-51}).

**Please replace Paragraph 2, lines 8-11, on Page 6 with the following:**

(HILLS B.A., Gastric mucosal barrier: evidence for *Helicobacter pylori* ingesting gastric surfactant and deriving protection from it. *Gut*. 1983 May; 34(5): 588-93.

**Please replace Paragraph 5, lines 21-24, on Page 6 with the following:**

GEIS G., LEYING H., SUERBAUM S., MAI U. & OPFERKUCH W.: Ultrastructure and chemical analysis of *Campylobacter pylori* flagella. *J. Clin. Microbiol*, 27; 436-441, 1989}).

**Please replace Paragraph 6, lines 25-29, on Page 6 with the following:**

b. *Klebsiella pneumoniae*

(C. ERBING, L. KENNE, B. LINBERG, J. LONNGREN (1976) – Structural studies of the capsular polysaccharide of *Klebsiella pneumoniae* type I (*Carbohydr. Res.*, 50 (1976) 115-20).

**Please replace Paragraph 1, lines 1-5, on Page 7 with the following:**

W. NIMMICH (1968) Zur Isolierung und qualitativen Bausteinanalyse der K. Antigen von Klebsiellen (Isolation of the *Klebsiella* K antigen and qualitative analysis of its structural components) (*Med. Mikrobiol. Immunol.*, 154, 117, 131).

**Please replace Paragraph 2, lines 6-9, on Page 7 with the following:**

C. RICHARD (1973) – Etude antigenique et biochemique de 500 souches de Klebsiella ({Antigenic and biochemical study of 500 Klebsiella strains}) (Ann. Biol. Clin., 1973)}).

**Please replace Paragraph 3, lines 10-12, on Page 7 with the following:**

c. *Streptococcus pneumoniae*:

({F. KAUFFMANN and E. LUND (1954) (Int. Bull. Bact. Nomencl. 4, 125-28).

**Please replace Paragraph 8, lines 24-27, on Page 7 with the following:**

C.P.J. GLAUDEMANS and H.P. TREFFERS – An improved preparation of the capsular polysaccharide from *Diplococcus pneumoniae* (Carbohydr. Res. 1967, 4, 181-84)}).

**Please replace Paragraph 1, lines 1-4, on Page 8 with the following:**

({P. ANDERSON et al. (1972) – Immunization of humans with polyribosephosphate, the capsular antigen of *Hemophilus influenzae* type B (J. of Clin. Invest., vol. 51, 1972, 39-44).

**Please replace Paragraph 2, lines 5-8, on Page 8 with the following:**

P. ANDERSON et al. (1977) – Isolation of the capsular polysaccharide from supernatant of *Hemophilus influenzae* type B (Infect. And Immun., 1977, 15 (2), 472-77)}).

**Please replace Paragraph 3, lines 9-12, on Page 8 with the following:**

e. *Escherichia coli* (capsular polysaccharides)

(LUDERITZ et al. (1977) – Somatic and capsular antigens of gram-negative bacteria (Compr. Biochem. 26 A, 105-228).

**Please replace Paragraph 6, lines 20-24, on Page 8 with the following:**

LUGTENBERG B., J. Meijers, R. Peters, P. van der Hock and L. van Alphen (1975) – Electrophoretic resolution of the "major outer membrane protein" of *Escherichia coli* K12 into four bands. (FEBS Lett. 58; 254-258).

**Please replace Paragraph 2, lines 10-12, on Page 9 with the following:**

(GOODWIN C.S. "Helicobacter Pylori: 10<sup>th</sup> anniversary of its culture in April 1982". (Gut 1993; 34: 293-4).

**Please replace Paragraph 1, lines 2-4, on Page 10 with the following:**

Y.B. KIM et al. (1967) – Biologically active endotoxins from Salmonella mutans (J. of Bacteriol., 94, (5), 1320-261).

**Please replace Paragraph 3, lines 23-29, on Page 14 and lines 1-5 on Page 15 with the following:**

This therapeutic (vaccine) complex may be assimilated to a specific vaccine (through an "inert system" which is intended to increase the immunogenicity of a recombinant subunit vaccine and of vaccines consisting of peptides), and a nonspecific vaccine with the characteristics of a lymphokine, which, by attaching to the macrophages, plays an essential role in the immune response towards Helicobacter (KAZI J.I.,

SINNIAH R., JAFFRAY N.A., ALAM S.M., ZAMAN V., ZUBERI S.J. & KAZI A.M.: Cellular and humoral immune response in *Campylobacter pylori*-associated chronic gastritis, J. Pathol. 159; 231-237, 1989}}

**Please replace Paragraph 6, lines 26-29, on Page 15 with the following:**

{{TRIEU-CUOT, P., G. GERBAUD, T. LAMBERT and P. COURVALIN (1985) – In vivo transfer of genetic information between gram-positive and gram-negative bacteria. (EMBO J. 4:3583-3587)}}.

**Please replace Paragraph 4, lines 15-18, on Page 16 with the following:**

{{ANDERSEN L.P.; NIELSEN H. Survival and ultrastructural changes of *Helicobacter pylori* after phagocytosis by human polymorphonuclear leukocytes and monocytes, APMIS; 1993 Jan.: 101(1); 61-72}}.

**Please replace Paragraph 5, lines 19-21, on Page 16 with the following:**

{{STEIGBIGEL R. T., LAMBERT L. H. & REMINGTON J.S.; Phagocytic and bactericidal properties of normal human monocytes, J. Clin. Invest. 53; 131-142, 1974}}.

**Please replace Paragraph 6, lines 22-24, on Page 16 with the following:**

{{YAM L.T., Li C.Y. & CROSBY W.H.; Cytochemical identification of monocytes and granulocytes, Am. J. Clin. Pathol. 55; 283-290, 1971}}.

**Please replace Paragraph 2, lines 9-13, on Page 18 with the following:**

{{KIST M; SPIEGELHALDER C.; MORIKI T.; SCHAEFER H.E. – Interaction of *Helicobacter pylori* (strain 151) and *Campylobacter coli* with human peripheral

polymorphonuclear granulocytes}}, and in preventing infectious recidivations (Zentralbl Bakferoil., 280 (1-2), pp. 58-72, (1993).

**Please replace Paragraph 6, lines 27-29, on Page 18 and lines 1-3 on Page 19 with the following:**

{{SUERBAUM S., C. JOSENHANS, and A. LABIGNE (1993) – Cloning and genetic characterization of the *Helicobacter pylori* and *Helicobacter mustelae* flaB flagellin genes and construction of *H. pylori* flaA - and flab-negative mutants by electroporation-mediated allelic exchange. (J. Bacteriol. 175:3278-3288).

**Please replace Paragraph 2, lines 9-12, on Page 19 with the following:**

- CHEN M. LEE A., HAZELL S., HU P., LI Y. – Protective immunisation against *Helicobacter*: the need for stimulation of common mucosal immune system (abstract). (Gastroenterology 1993, 104 (suppl): A681)}.